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09/787,111	05/14/2001	Louis Schofield	18861	1473

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EXAMINER	
MINNIFIELD, NITA M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/787,111	SCHOFIELD, LOUIS	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38 and 54-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38 and 54-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed March 24, 2008 is acknowledged and has been entered. Claims 1-37 and 39-53 have been canceled. Claim 38 has been amended. Claims 38 and 54-61 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 38 and 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Schofield et al 1996 (Journal of Immunology, 156:1886-1896).

Schofield et al 1996 discloses a GPI of malaria parasite origin and in PBS, water or buffer of choice (abstract; p. 1887). Schofield et al 1996 discloses mAb to malarial GPI (p. 1887).

Although the prior art does not specifically disclose that the lipidic domain is incapable of inducing an immune response, it would appear that no immune response is induce directed to the lipidic domain of said GPI.

Further, it is noted that the specification defines derivatives and equivalents "…to be understood to include fragments, parts, portions, chemical equivalents, mutants, homologs and analogs. Chemical equivalents of a GPI inositolglycan domain can act as a functional analog of the GPI inositolglycan domain. For

example, a chemical equivalent of the GPI inositolglycan domain includes a GPI inositolglycan domain in which the phosphoglycerol component of the inositolglycan has been modified to increase hydrophobicity. This may be achieved by replacement with truncated, partial or modified fatty acids or other hydrophobic moieties and acts to improve the immunogenicity or stability of the molecule, without generating an undesirable antibody response. Chemical equivalents may not necessarily be derived from a GPI inositolglycan domain but may share certain conformational similarities. Alternatively, chemical equivalents may be specifically designed to mimic certain immunological and physiochemical properties of the GPI inositolglycan domain. Chemical equivalents may be chemically synthesised or may be detected following, for example, natural product screening. Chemical equivalents also include synthetic carbohydrates and peptide mimics. Homologs of GPI inositolglycan domains contemplated herein include, but are not limited to, GPI inositolglycan domains from different species including, for example, Saccharomyces. Fragments, include portions such as the glycan component of the inositolglycan domain, which portions are effective in achieving the object of the present invention." (see specification pp. 15-16).

It would appear that the prior art discloses the claimed GPI molecule. Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

With regard to the prior art rejection, it is noted that the reference discloses the composition and that the function (induces an immune response directed to a micro-organism GPI inositolglycan domain but is incapable of inducing an immune response directed to a lipidic domain of said GPI) or properties are inherent so long as the claimed product components are disclosed in the prior art. Further, it is noted that Applicant is not claiming a method of inducing an immune response, but rather a product, a modified GPI, which the prior art discloses. The "modified GPI molecule or derivative or equivalent thereof" is not specifically defined.

Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed March 24, 2008 have been fully considered but they are not persuasive. Applicant has asserted that Schofield et al does not disclose preparation of the immunogenic portion of the GPI that provides protective immunity and that the reference does not possess the properties encompassed by antibodies obtained by immunization with the claimed composition. However, it is the Examiner's position the Applicant argues limitations that are not recited in the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., "protective immunity"; "protective antibodies"; "antibodies") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that Applicant has argued process limitations (reference does not disclose preparation of the immunogenic portion of GPI…p. 7 of Remarks); however the instant claims are directed to a product, a composition comprising a modified GPI molecule. Further, a precursor would appear to be a derivative or equivalent thereof. As previously stated, neither the claims nor the specification clearly define derivatives or equivalents. The specification states that they are understood to include fragments, parts, portions, chemical equivalents, mutants, homologs and analogs. Therefore, a precursor would appear to be a fragment, part or portion. The claims recite that the lipidic domain in the modified GPI molecule is incapable of inducing or eliciting an immune response, not that the GPI is de-lipidated (i.e. no lipid at all).

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103

rejection is appropriate for these types of claims as well as for composition claims. (see MPEP 2112)

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). (see MPEP 2112.01)

4. Claims 38 and 54-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims recite a modified GPI molecule or derivative or equivalent thereof which induces an immune response directed to a microorganism GPI inositolglycan domain but is incapable of inducing an immune response directed to a lipidic domain of said GPI. Claim 60 recites that X1, X2, X3, X4 are any 4 amino acids.

The specification broadly describes that “"Derivatives" and "equivalents" should be understood to include fragments, parts, portions, chemical equivalents, mutants, homologs and analogs. Chemical equivalents of a GPI inositolglycan domain can act as a functional analog of the GPI inositolglycan domain. For example, a chemical equivalent of the GPI inositolglycan domain includes a GPI inositol-glycan domain in which the phosphoglycerol component of the inositolglycan has been modified to increase hydrophobicity. This may be achieved by replacement with truncated, partial or modified fatty acids or other hydrophobic moieties and acts to improve the immunogenicity or stability of the molecule, without generating an undesirable antibody response. Chemical equivalents may not necessarily be derived from a GPI inositolglycan domain but may share certain confirmational similarities. Alternatively, chemical equivalents may be specifically designed to mimic certain immunological and physiochemical properties of the GPI inositolglycan domain. Chemical equivalents may be chemically synthesised or may be detected following, for example, natural product screening. Chemical equivalents also include synthetic carbohydrates and peptide mimics. Homologs of GPI inositolglycan domains contemplated herein include, but are not limited to, GPI inositolglycan domains from different species including, for example, Saccharomyces. Fragments, include portions such as the glycan component of the inositolglycan domain, which portions are effective in achieving the object of the present invention.” (pp. 15-16)

Since the instant specification discloses the term “derivative”, the instant specification teaches that any modification may be made within the structure of a modified GPI. The instant specification does not provide written description for all derivatives or equivalents thereof encompassed by the claimed invention. The

claimed invention encompasses derivatives and equivalents of a modified GPI that have *not been discovered yet.* The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The specification as filed does not provide written description support for derivative or equivalent; the skilled artisan cannot envision all the contemplated substances by the label "derivative" or "equivalents" and therefore conception cannot be not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and along with a recitation of a function such as inducing Th cells. The derivative or equivalent itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)and Am.qen Inc. V. Chu,qai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

In addition, a definition by function does not suffice to define the genus because it is only an indication of what the property the peptide has, and if one extends the analysis in the instant case, what the peptide does rather than what it is. See Fiers, 984 F.2d at 1169-71,25 USPQ2d at 1605-06. It is only a definition of a useful result rather than a definition of what achieves that result. Many such

species may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. One of ordinary skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

The skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives or chemical equivalents thereof of modified GPI. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

The state of the art teaches that GPI anchor moieties or modification have not been successful in the treatment or protection against malaria. Gowda et al states that “[D]epsite the possibility that detailed knowledge of the parasite GPI anchor structure, function and biosynthesis could provide attractive targets for anti-malarial drug development, such studies have not received wide attention. If GPI

anchors are pathogenicity factors, the precise molecular mechanism of action of the host needs to be established, as does the GPI biosynthesis pathway. Other aspects that remain unanswered are: (1) the identity and significance of the unusual substituents on the glycan moieties of *P. falciparum* protein GPI anchors; (2) whether GPI anchors are involved in membrane modifications that occur during the parasite invasion of red blood cells and in exporting functional proteins to the erythrocyte surface; (3) whether the parasite GPI anchors released into the host bloodstream contribute to immune-mediated cell lysis, a possible cause of tissue injury; and (4) whether anti-GPI anchor moieties are involved in host anti-disease immune response." (see p. 151, col. 1).

The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) One of skill in the art would not envision that Applicant was in possession of the *infinite* genus of derivatives or equivalents thereof of modified GPI as broadly claimed since the instant specification discloses that the instant specification encompasses *othe*r derivatives or equivalents thereof. Thus, Applicant has not satisfied the requirements as set forth under 35 U.S.C. 112 first paragraph.

The rejection is maintained for the reasons of record. Applicant's arguments filed March 24, 2008 have been fully considered but they are not persuasive. Applicant has asserted that amendment to the claims to recite that the claimed subject matter possesses at least three residues of the core glycan portion of the

modified GPI domain. However the recitation that the modified GPI domain possesses at least three residues of the core glycan portion does not address the number of possibilities for the modified GPI since the claims recite derivatives or equivalents thereof. As previously stated the specification broadly describes that “"Derivatives" and "equivalents" should be understood to include fragments, parts, portions, chemical equivalents, mutants, homologs and analogs. Chemical equivalents of a GPI inositolglycan domain can act as a functional analog of the GPI inositolglycan domain. For example, a chemical equivalent of the GPI inositolglycan domain includes a GPI inositol-glycan domain in which the phosphoglycerol component of the inositolglycan has been modified to increase hydrophobicity. This may be achieved by replacement with truncated, partial or modified fatty acids or other hydrophobic moieties and acts to improve the immunogenicity or stability of the molecule, without generating an undesirable antibody response. Chemical equivalents may not necessarily be derived from a GPI inositolglycan domain but may share certain confirmational similarities. Alternatively, chemical equivalents may be specifically designed to mimic certain immunological and physiochemical properties of the GPI inositolglycan domain. Chemical equivalents may be chemically synthesised or may be detected following, for example, natural product screening. Chemical equivalents also include synthetic carbohydrates and peptide mimics. Homologs of GPI inositolglycan domains contemplated herein include, but are not limited to, GPI inositolglycan domains from different species including, for example, Saccharomyces. Fragments, include portions such as the glycan component of the inositolglycan domain, which portions are effective in achieving the object of the present invention.” (pp. 15-16) Even though the claims now recite the

requirement that the modified GPI have at least three residues of the core glycan, the scope of the genus of derivatives or equivalents thereof, this recitation is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus, and thus, that the applicant was not in possession of the claimed genus. The claimed subject matter is not supported by an adequate written description because a representative number of species has not been described.

Since the instant specification discloses the term “derivative”, the instant specification teaches that any modification may be made within the structure of a modified GPI. The instant specification does not provide written description for all derivatives or equivalents thereof encompassed by the claimed invention. The claimed invention encompasses derivatives and equivalents of a modified GPI that have *not been discovered yet.* The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

One of skill in the art would not envision that Applicant was in possession of the *infinite* genus of derivatives or equivalents thereof of modified GPI as broadly claimed since the instant specification discloses that the instant specification encompasses *othe*r derivatives or equivalents thereof.

Thus, Applicant has not satisfied the requirements as set forth under 35 U.S.C. 112 first paragraph.

5. The amendment filed March 24, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "wherein the derivative or equivalent comprises at least three residues of the core glycan of the modified GPI molecule". This recitation nor the concept of having at least three residues of the core glycan is found in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

6. Claims 38 and 54-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim limitation of "wherein the derivative or equivalent comprises at least three residues of the core glycan of the modified GPI molecule" does not find support in the instant specification. This recitation nor the concept of having at least three residues of the core glycan is found in the specification. This is a new matter rejection. The phrase sets forth a specific species "having at least three residues of the core glycan" that is not supported by or specifically described in the specification.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Shanon Foley can be reached on 571-272-8975. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. Minnifield/
Primary Examiner,
Art Unit 1645
July 22, 2008